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Patent

### IN THE CLAIMS

In accordance with the newly instituted revised amendment format, a complete set of claims follows, with new material to be added to the claims shown as underlined, and material to be deleted shown as ~~struck through~~.

1-84 (Previously cancelled)

85. (Previously added) An assay for determining the presence or amount of a free and complexed cardiac specific isoform of troponin in a patient sample, said assay comprising:

performing an immunoassay with an antibody which specifically binds said free cardiac specific isoform of troponin, and which specifically binds said cardiac specific isoform of troponin in a binary complex comprising one other troponin component selected from the group consisting of troponin I, troponin C and troponin T, and which specifically binds said cardiac specific isoform of troponin in a ternary complex comprising two other troponin components selected from the group consisting of troponin I, troponin C and troponin T; and

detecting a signal from said immunoassay resulting from said antibody binding said free and complexed cardiac specific isoform of troponin, wherein said signal is at least a factor of two larger than a signal resulting from said antibody binding to an equal number of (i) free troponin components which are not said cardiac specific isoform of troponin; (ii) troponin complexes which do not comprise said cardiac specific isoform of troponin; or (iii) a combination of (i) and (ii), and wherein said signal is related to the presence or amount of said free and complexed cardiac specific isoform of troponin in said sample.

86. (Previously added) An assay according to claim 85, wherein said patient sample is selected from the group consisting of a blood sample, a serum sample, and a plasma sample.

87. (Previously amended) An assay according to claim 85, wherein said signal from said immunoassay resulting from said antibody binding said free and complexed cardiac specific



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isoform of troponin is at least a factor of five greater than said signal resulting from said antibody binding to an equal number of (i) free troponin components which are not said cardiac specific isoform of troponin; (ii) troponin complexes which do not comprise said cardiac specific isoform of troponin; or (iii) a combination of (i) and (ii).

88. (Previously amended) An assay for determining the presence or amount of [a] free and complexed cardiac specific isoforms of troponin in a patient sample, said assay comprising:

performing an immunoassay with an antibody which specifically binds to free cardiac specific troponin I and cardiac specific troponin T, and which specifically binds to cardiac specific troponin I and cardiac specific troponin T in a complex comprising at least one other troponin component selected from the group consisting of troponin I, troponin C and troponin T, and which specifically binds to cardiac specific troponin I and cardiac specific troponin T in a ternary complex comprising two other troponin components selected from the group consisting of troponin I, troponin C and troponin T; and

detecting a signal from said immunoassay resulting from said antibody binding said free and complexed cardiac specific isoforms of troponin, wherein said signal is at least a factor of two larger than a [minimum] signal resulting from said antibody binding to an equal number of (i) free troponin components which are not said cardiac specific isoforms of troponin; (ii) troponin complexes which do not comprise said cardiac specific isoforms of troponin; or (iii) a combination of (i) and (ii), and wherein said signal is related to the presence or amount of said free and complexed cardiac specific isoforms of troponin in said sample.

89. (Previously added) An assay according to claim 88, wherein said patient sample is selected from the group consisting of a blood sample, a serum sample, and a plasma sample.

90. (Previously amended) An assay according to claim 88, wherein said signal from said immunoassay resulting from said antibody binding said free and complexed cardiac specific isoforms of troponin is at least a factor of five greater than said signal resulting from said



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antibody binding to an equal number of (i) free troponin components which are not said cardiac specific isoforms of troponin; (ii) troponin complexes which do not comprise said cardiac specific isoforms of troponin; or (iii) a combination of (i) and (ii).

91. (Previously added) An assay for determining the presence or amount of free and complexed cardiac specific troponin I in a patient sample, said assay comprising:

performing an immunoassay with an antibody which specifically binds to free cardiac specific troponin I, and which specifically binds to cardiac specific troponin I in a complex comprising at least one other troponin component selected from the group consisting of troponin C and troponin T, and which specifically binds to cardiac specific troponin I in a ternary complex comprising troponin C and troponin T; and

detecting a signal from said immunoassay resulting from said antibody binding said free and complexed cardiac specific troponin I, wherein said signal is at least a factor of two larger than a signal resulting from said antibody binding to an equal number of (i) free troponin components which are not said cardiac specific troponin I; (ii) troponin complexes which do not comprise said cardiac specific troponin I; or (iii) a combination of (i) and (ii), and wherein said detectable signal is related to the presence or amount of said free and complexed cardiac specific troponin I in said sample.

92. (Previously added) An assay according to claim 91, wherein said patient sample is selected from the group consisting of a blood sample, a serum sample, and a plasma sample.

93. (Previously amended) An assay according to claim 91, wherein said signal from said immunoassay resulting from said antibody binding said free and complexed cardiac specific troponin I is at least a factor of five greater than said signal resulting from said antibody binding to an equal number of (i) free troponin components which are not said cardiac specific troponin I; (ii) troponin complexes which do not comprise said cardiac specific troponin I; or (iii) a combination of (i) and (ii).



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94. (Previously added) An assay for determining the presence or amount of free and complexed cardiac specific troponin T in a patient sample, said assay comprising:

performing an immunoassay with an antibody which specifically binds to free cardiac specific troponin T, and which specifically binds to cardiac specific troponin T in a complex comprising at least one other troponin component selected from the group consisting of troponin C and troponin I, and which specifically binds to cardiac specific troponin T in a ternary complex comprising troponin C and troponin I; and

detecting a signal from said immunoassay resulting from said antibody binding said free and complexed cardiac specific troponin T, wherein said signal is at least a factor of two larger than a signal resulting from said antibody binding to an equal number of (i) free troponin components which are not said cardiac specific troponin T; (ii) troponin complexes which do not comprise said cardiac specific troponin T; or (iii) a combination of (i) and (ii), and wherein said detectable signal is related to the presence or amount of said free and complexed cardiac specific troponin T in said sample.

95. (Previously added) An assay according to claim 94, wherein said patient sample is selected from the group consisting of a blood sample, a serum sample, and a plasma sample.

96. (Previously amended) An assay according to claim 94, wherein said signal from said immunoassay resulting from said antibody binding said free and complexed cardiac specific troponin T is at least a factor of five greater than said signal resulting from said antibody binding to an equal number of (i) free troponin components which are not said cardiac specific troponin T; (ii) troponin complexes which do not comprise said cardiac specific troponin T; or (iii) a combination of (i) and (ii).

97-101 (Previously cancelled)

102. (Previously added) An assay for determining the presence or amount of all free and complexed cardiac specific isoforms of troponin in a patient sample, said assay comprising:



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performing an immunoassay with an antibody which specifically binds all free cardiac specific isoforms of troponin, and which specifically binds all cardiac specific isoforms of troponin in a complex comprising at least one other troponin component selected from the group consisting of troponin I, troponin C and troponin T, and which specifically binds all cardiac specific isoforms of troponin in a ternary complex comprising two other troponin components selected from the group consisting of troponin I, troponin C and troponin T; and

detecting a signal from said immunoassay resulting from said antibody binding said free and complexed cardiac specific isoforms of troponin, wherein said signal is related to the presence or amount of all free and complexed cardiac specific isoforms of troponin in said sample.

103. (Previously added) An assay according to claim 102, wherein said patient sample is selected from the group consisting of a blood sample, a serum sample, and a plasma sample.

104. (Previously added) An assay according to claim 102, wherein said signal is approximately equal for equal amounts of all cardiac specific isoforms of troponin.

105. (Previously amended) An assay according to claim 102, wherein said signal is within 20% for equal amounts of all cardiac specific isoforms of troponin.

106. (Previously added) An assay according to claim 102, wherein said signal is within a factor of 2 for equal amounts of all cardiac specific isoforms of troponin.

107-113 (Previously cancelled)

114. (Previously added) An assay for determining the presence or amount of a free and complexed cardiac specific isoforms of troponin in a patient sample, said assay comprising:

performing an immunoassay with an antibody which specifically binds said free cardiac specific isoform of troponin, and which specifically binds said cardiac specific isoform of troponin in a complex comprising at least one other troponin component selected from the group consisting of troponin I, troponin C and troponin T, and which specifically binds said cardiac



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specific isoform of troponin in a ternary complex comprising two other troponin components selected from the group consisting of troponin I, troponin C and troponin T; and

detecting a signal from said immunoassay resulting from said antibody binding said free and complexed cardiac specific isoform of troponin, wherein said signal is related to the presence or amount of said free and complexed cardiac specific isoforms of troponin in said sample.

115. (Previously added) An assay according to claim 114, wherein said patient sample is selected from the group consisting of a blood sample, a serum sample, and a plasma sample.

116. (Previously amended) An assay according to claim 114, wherein a signal detected from said immunoassay for an amount of said free cardiac specific isoform of troponin is approximately equal to a signal detected from said immunoassay for an equal amount of said complexed cardiac specific isoform of troponin.

117. (Previously amended) An assay according to claim 114, wherein a signal detected from said immunoassay for an amount of said free cardiac specific isoform of troponin is within 20% of a signal detected from said immunoassay for an equal amount of said complexed cardiac specific isoform of troponin.

118. (Previously amended) An assay according to claim 114, wherein a signal detected from said immunoassay for an amount of said free cardiac specific isoform of troponin is within a factor of 2 of a signal detected from said immunoassay for an equal amount of said complexed cardiac specific isoform of troponin.

119. (Previously amended) An assay for determining the presence or amount of free and complexed cardiac specific isoforms of troponin in a patient sample, said assay comprising:

performing an immunoassay with an antibody which specifically binds to free cardiac specific troponin I and free cardiac specific troponin T, and which specifically binds to cardiac specific troponin I and cardiac specific troponin T in a complex comprising at least one other



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troponin component selected from the group consisting of troponin I, troponin C and troponin T, and which specifically binds to cardiac specific troponin I and cardiac specific troponin T in a ternary complex comprising two other troponin components selected from the group consisting of troponin I, troponin C and troponin T; and

detecting a signal from said immunoassay resulting from said antibody binding said free and complexed cardiac specific isoforms of troponin, wherein said signal is related to the presence or amount of said free and complexed cardiac specific isoforms of troponin in said sample.

120. (Previously added) An assay according to claim 119, wherein said patient sample is selected from the group consisting of a blood sample, a serum sample, and a plasma sample.

121. (Previously amended) An assay according to claim 119, wherein a signal detected from said immunoassay for an amount of said free cardiac specific isoforms of troponin is approximately equal to a signal detected from said immunoassay for an equal amount of said complexed cardiac specific isoforms of troponin.

122. (Previously amended) An assay according to claim 119, wherein a signal detected from said immunoassay for an amount of said free cardiac specific isoforms of troponin is within 20% of a signal detected from said immunoassay for an equal amount of said complexed cardiac specific isoforms of troponin.

123. (Previously amended) An assay according to claim 119, wherein a signal detected from said immunoassay for an amount of said free cardiac specific isoforms of troponin is within a factor of 2 of a signal detected from said immunoassay for an equal amount of said complexed cardiac specific isoforms of troponin.

124. (Previously amended) An assay for determining the presence or amount of free and complexed cardiac specific troponin I in a patient sample, said assay comprising:



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performing an immunoassay with an antibody which specifically binds to free cardiac specific troponin I, and which specifically binds to cardiac specific troponin I in a complex comprising at least one other troponin component selected from the group consisting of troponin C and troponin T, and which specifically binds to cardiac specific troponin I in a ternary complex comprising troponin C and troponin T; and

detecting a signal from said immunoassay resulting from said antibody binding said free and complexed cardiac specific troponin I, wherein said signal is related to the presence or amount of said free and complexed cardiac specific troponin I in said sample.

125. (Previously added) An assay according to claim 124, wherein said patient sample is selected from the group consisting of a blood sample, a serum sample, and a plasma sample.

126. (Previously amended) An assay according to claim 124, wherein a signal detected from said immunoassay for an amount of said free cardiac specific troponin I is approximately equal to a signal detected from said immunoassay for an equal amount of said complexed cardiac specific troponin I.

127. (Previously amended) An assay according to claim 124, wherein a signal detected from said immunoassay for an amount of said free cardiac specific troponin I is within 20% of a signal detected from said immunoassay for an equal amount of said complexed cardiac specific troponin I.

128. (Previously amended) An assay according to claim 124, wherein a signal detected from said immunoassay for an amount of said free cardiac specific troponin I is within a factor of 2 of a signal detected from said immunoassay for an equal amount of said complexed cardiac specific troponin I.

129. (Previously amended) An assay for determining the presence or amount of free and complexed cardiac specific troponin T in a patient sample, said assay comprising:



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performing an immunoassay with an antibody which specifically binds to free cardiac specific troponin T, and which specifically binds to cardiac specific troponin T in a complex comprising at least one other troponin component selected from the group consisting of troponin I and troponin C, and which specifically binds to cardiac specific troponin I in a ternary complex comprising troponin I and troponin C; and

detecting a signal from said immunoassay resulting from said antibody binding said free and complexed cardiac specific troponin T, wherein said signal is related to the presence or amount of said free and complexed cardiac specific troponin T in said sample.

130. (Previously added) An assay according to claim 129, wherein said patient sample is selected from the group consisting of a blood sample a serum sample, and a plasma sample.

131. (Previously amended) An assay according to claim 129, wherein a signal detected from said immunoassay for an amount of said free cardiac specific troponin T is approximately equal to a signal detected from said immunoassay for an equal amount of said complexed cardiac specific troponin T.

132. (Previously amended) An assay according to claim 129, wherein a signal detected from said immunoassay for an amount of said free cardiac specific troponin T is within 20% of a signal detected from said immunoassay for an equal amount of said complexed cardiac specific troponin T.

133. (Previously amended) An assay according to claim 129, wherein a signal detected from said immunoassay for an amount of said free cardiac specific troponin T is within a factor of 2 of a signal detected from said immunoassay for an equal amount of said complexed cardiac specific troponin T.

134. (Amended herein) An assay for determining the presence or amount of a free and complexed cardiac specific isoform of troponin in a patient sample, said assay comprising:



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~~performing an immunoassay with~~ An assay according to claim 85, wherein said antibody  
is an antibody cocktail which specifically binds said free cardiac specific isoform of troponin,  
and which specifically binds said cardiac specific isoform of troponin in a binary complex  
comprising one other troponin component selected from the group consisting of troponin I,  
troponin C and troponin T, and which specifically binds said cardiac specific isoform of troponin  
in a ternary complex comprising two other troponin components selected from the group  
consisting of troponin I, troponin C and troponin T; and

detecting a signal from said immunoassay resulting from said antibody cocktail binding said free  
and complexed cardiac specific isoform of troponin, wherein said signal is at least a factor of two  
larger than a signal resulting from said antibody binding to an equal number of (i) free troponin  
components which are not said cardiac specific isoform of troponin; (ii) troponin complexes  
which do not comprise said cardiac specific isoform of troponin; or (iii) a combination of (i) and  
(ii), and wherein said signal is related to the presence or amount of said free and complexed  
cardiac specific isoform of troponin in said sample.

135. (Amended herein) An assay for determining the presence or amount of [a] free and  
complexed cardiac specific isoforms of troponin in a patient sample, said assay comprising:

~~performing an immunoassay with~~ An assay according to claim 88, wherein said antibody  
is an antibody cocktail which specifically binds to free cardiac specific troponin I and cardiac  
specific troponin T, and which specifically binds to cardiac specific troponin I and cardiac  
specific troponin T in a complex comprising at least one other troponin component selected from  
the group consisting of troponin I, troponin C and troponin T, and which specifically binds to  
cardiac specific troponin I and cardiac specific troponin T in a ternary complex comprising two  
other troponin components selected from the group consisting of troponin I, troponin C and  
troponin T; and

detecting a signal from said immunoassay resulting from said antibody cocktail binding said free  
and complexed cardiac specific isoforms of troponin, wherein said signal is at least a factor of



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two larger than a [minimum] signal resulting from said antibody binding to an equal number of (i) free troponin components which are not said cardiac specific isoforms of troponin; (ii) troponin complexes which do not comprise said cardiac specific isoforms of troponin; or (iii) a combination of (i) and (ii), and wherein said signal is related to the presence or amount of said free and complexed cardiac specific isoforms of troponin in said sample.

136. (Amended herein) An assay for determining the presence or amount of free and complexed cardiac specific troponin I in a patient sample, said assay comprising:

performing an immunoassay with ~~An assay according to claim 91, wherein said antibody~~ is an antibody cocktail which specifically binds to free cardiac specific troponin I and which specifically binds to cardiac specific troponin I in a complex comprising at least one other troponin component selected from the group consisting of troponin C and troponin T, and which specifically binds to cardiac specific troponin I in a ternary complex comprising troponin C and troponin T; and

detecting a signal from said immunoassay resulting from said antibody cocktail binding said free and complexed cardiac specific troponin I, wherein said signal is at least a factor of two larger than a signal resulting from said antibody binding to an equal number of (i) free troponin components which are not said cardiac specific troponin I; (ii) troponin complexes which do not comprise said cardiac specific troponin I; or (iii) a combination of (i) and (ii), and wherein said detectable signal is related to the presence or amount of said free and complexed cardiac specific troponin I in said sample.

137. (Amended herein) An assay for determining the presence or amount of free and complexed cardiac specific troponin T in a patient sample, said assay comprising:

performing an immunoassay with ~~An assay according to claim 94, wherein said antibody~~ is an antibody cocktail which specifically binds to free cardiac specific troponin T, and which specifically binds to cardiac specific troponin T in a complex comprising at least one other



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troponin component selected from the group consisting of troponin C and troponin I, and which specifically binds to cardiac specific troponin T in a ternary complex comprising troponin C and troponin I; and

detecting a signal from said immunoassay resulting from said antibody cocktail binding said free and complexed cardiac specific troponin T, wherein said signal is at least a factor of two larger than a signal resulting from said antibody binding to an equal number of (i) free troponin components which are not said cardiac specific troponin T; (ii) troponin complexes which do not comprise said cardiac specific troponin T; or (iii) a combination of (i) and (ii), and wherein said detectable signal is related to the presence or amount of said free and complexed cardiac specific troponin T in said sample.

138. (Amended herein) An assay for determining the presence or amount of all free and complexed cardiac specific isoforms of troponin in a patient sample, said assay comprising:

performing an immunoassay with ~~An assay according to claim 102, wherein said antibody~~ is an antibody cocktail which specifically binds all free cardiac specific isoforms of troponin, and which specifically binds all cardiac specific isoforms of troponin in a complex comprising at least one other troponin component selected from the group consisting of troponin I, troponin C and troponin T, and which specifically binds all cardiac specific isoforms of troponin in a ternary complex comprising two other troponin components selected from the group consisting of troponin I, troponin C and troponin T; and

detecting a signal from said immunoassay resulting from said antibody cocktail binding said free and complexed cardiac specific isoforms of troponin, wherein said signal is related to the presence or amount of all free and complexed cardiac specific isoforms of troponin in said sample.

139. (Amended herein) An assay for determining the presence or amount of a free and complexed cardiac specific isoform of troponin in a patient sample, said assay comprising:



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performing an immunoassay with ~~An assay according to claim 114, wherein said antibody~~  
is an antibody cocktail which specifically binds said free cardiac specific isoform of troponin,  
and which specifically binds said cardiac specific isoform of troponin in a complex comprising at  
least one other troponin component selected from the group consisting of troponin I, troponin C  
and troponin T, and which specifically binds said cardiac specific isoform of troponin in a ternary  
complex comprising two other troponin components selected from the group consisting of  
troponin I, troponin C and troponin T; and

detecting a signal from said immunoassay resulting from said antibody cocktail binding said free  
and complexed cardiac specific isoform of troponin, wherein said signal is related to the presence  
or amount of said free and complexed cardiac specific isoforms of troponin in said sample.

140. (Amended herein) An assay for determining the presence or amount of free and  
complexed cardiac specific isoforms of troponin in a patient sample, said assay comprising:

performing an immunoassay with ~~An assay according to claim 119, wherein said antibody~~  
is an antibody cocktail which specifically binds to free cardiac specific troponin I and free  
cardiac specific troponin T, and which specifically binds to cardiac specific troponin I and  
cardiac specific troponin T in a complex comprising at least one other troponin component  
selected from the group consisting of troponin I, troponin C and troponin T, and which  
specifically binds to cardiac specific troponin I and cardiac specific troponin T in a ternary  
complex comprising two other troponin components selected from the group consisting of  
troponin I, troponin C and troponin T; and

detecting a signal from said immunoassay resulting from said antibody cocktail binding said free  
and complexed cardiac specific isoforms of troponin, wherein said signal is related to the  
presence or amount of said free and complexed cardiac specific isoforms of troponin in said  
sample.

141. (Amended herein) An assay for determining the presence or amount of free and  
complexed cardiac specific troponin I in a patient sample, said assay comprising:



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performing an immunoassay with ~~An assay according to claim 124, wherein said antibody~~  
~~is an antibody cocktail which specifically binds to free cardiac specific troponin I, and which~~  
~~specifically binds to cardiac specific troponin I in a complex comprising at least one other~~  
~~troponin component selected from the group consisting of troponin C and troponin T, and which~~  
~~specifically binds to cardiac specific troponin I in a ternary complex comprising troponin C and~~  
~~troponin T; and~~

detecting a signal from said immunoassay resulting from said antibody cocktail binding  
said free and complexed cardiac specific troponin I, wherein said signal is related to the presence  
or amount of said free and complexed cardiac specific troponin I in said sample.

142. (Amended herein) An assay for determining the presence or amount of free and  
complexed cardiac specific troponin T in a patient sample, said assay comprising:

performing an immunoassay with ~~An assay according to claim 129, wherein said antibody~~  
~~is an antibody cocktail which specifically binds to free cardiac specific troponin T, and which~~  
~~specifically binds to cardiac specific troponin T in a complex comprising at least one other~~  
~~troponin component selected from the group consisting of troponin I and troponin C, and which~~  
~~specifically binds to cardiac specific troponin I in a ternary complex comprising troponin I and~~  
~~troponin C; and~~

detecting a signal from said immunoassay resulting from said antibody cocktail binding  
said free and complexed cardiac specific troponin T, wherein said signal is related to the  
presence or amount of said free and complexed cardiac specific troponin T in said sample.